CC: SEA

February 22, 1999

DRAFT - Give me

Your comments thoughts Fi
by 3/5 Greg

Procedures for Responding to Audit Policy Self-Disclosures

1. Upon receipt of a self-disclosure, copies should immediately be forwarded to Joel Blumstein and Gerry Sotolongo. Gerry will have a Planning & Evaluation staff person log the self-disclosure into DOCKET and METS.

Note: In order to be eligible for penalty mitigation under the audit policy, the self-disclosure must be in writing and must be received within 10 days of discovery of the violation. [Note that HQ is considering enlarging the ten-day requirement and has been willing to consider case-by-case exceptions to this rule.] Thus, telephone notifications and other non-written forms of notification can not be accepted.

Note: The audit policy need not be specifically referenced in the notification in order to be potentially eligible under the audit policy. Thus, any voluntary self-disclosure should be treated in accordance with these procedures.

Note: In the past, self-disclosures have been addressed to various people at EPA and we will continue to accept these self-disclosures without regard to whom they are addressed, as long as it is clear that the entity is self-disclosing a violation. For sake of consistency, if asked, entities should be directed to send their disclosures to Joel Blumstein. Also, to accelerate the process of responding to self-disclosures, entities should be encouraged to include in their disclosures a complete discussion of how each of the criteria in the audit policy have been satisfied.

2. Upon receipt of a copy of the self-disclosure, Joel will ask Sam/Ken to include it on the agenda for the weekly (Tuesday morning) enforcement managers meeting. At that meeting, copies of the self-disclosure will be distributed to the appropriate technical managers. Agreement will be reached at the enforcement managers meeting or shortly thereafter as to which staff person will take the lead in responding to the disclosure. (In cases where it is obvious as to who the appropriate staff person should be, such as when the disclosure is made pursuant to an initiative being handled by a particular individual, it will not be necessary to discuss the self-disclosure at an enforcement managers meeting and that individual will be presumed to be assigned.) The assigned staff person will generally be an engineer/scientist from one of the three technical enforcement offices but, on occasion, may be a regulatory office attorney.

Note: Even if violations under more than one program are disclosed, an effort should be made to assign a single staff person to coordinate the response. That person should consult as necessary with staff in other programs.

3. Immediately upon assignment, a letter should be sent to the person making the self-disclosure, acknowledging our receipt of the self-disclosure and giving a contact point and some information about the process that will be followed in considering the self-disclosure. See Attachment A.

7. If a determination is made that all of the criteria for full penalty mitigation are satisfied (i.e., all conditions met and no significant economic benefit) and no injunctive relief is necessary, a letter should be sent to the facility acknowledging the disclosure and stating that EPA has determined that the criteria for full penalty mitigation have been satisfied. See Attachment D for model letter. A case conclusion data sheet should be completed in order to close out the matter and Joel Blumstein should be notified that the case has been resolved. METS data entry should be performed by the program office METS coordinator.

Note: In order to satisfy HQ information needs, an estimate will need to be made of what penalty would have been sought in the case if the audit policy had not been applied. A detailed penalty calculation is not necessary in this situation.

- 7. If a determination is made that the criteria for full penalty mitigation are not satisfied (i.e., criteria D.1 not satisfied/75% gravity mitigation allowed; one of criteria D.2-9 not satisfied/no mitigation under audit policy allowed; or, significant economic benefit) or injunctive relief is necessary and that the matter does not qualify under the small business policy, the matter will need to be resolved through a formal enforcement mechanism. Attorney support for the case should be sought at this stage. In most cases, we should be prepared to pre-negotiate these matters and to offer whatever mitigation is available under the audit policy and/or the applicable program penalty policies. A set period of time should be established for these pre-negotiations, in accordance with the Region's "Revised Prenegotiation Policy." Where pre-negotiations are successful, a simultaneous complaint and consent agreement would be filed. A case conclusion data sheet should be completed in order to close out the matter and Joel Blumstein should be notified that the case has been resolved. METS data entry should be performed by the program office METS coordinator. If negotiations are not successful, an administrative complaint (or, in appropriate cases, a judicial referral) should be prepared and issued in accordance with programspecific penalty and enforcement response policies. When the matter is resolved, a case conclusion data sheet should be completed in order to close out the matter and Joel Blumstein should be notified that the case has been resolved. METS data entry should be performed by the program office METS coordinator.
 - 8. Joel Blumstein will track progress in the resolution of audit policy matters and will brief the enforcement managers on a quarterly basis regarding unresolved matters.

Facsimile Transmission Cover Sheet



Erin Russell Clariant Corporation 4000 Monroe Road Charlotte NC 28205

Tel: 704/331-7059 Fax: 704/331-7131

erin.russell@clariant.com

To:

Ms. Deborah Brown

Firm:

EPA Region 1 617 918 0706

Fax No.: Phone:

617 918 1706

From:

Erin Russell

Date:

September 30, 2003

Subject:

Correspondence Attached

Number of pages, including cover:

5

CONFIDENTIALITY NOTE: The information contained in this telecopy is being transmitted to and is intended for the use of the individual named above. If the reader of this message is not the intended recipient, you are hereby advised that any dissemination, distribution or copy of this telecopy is strictly prohibited. If you have received this facsimile in error, please immediately notify us by telephone and destroy this telecopy.

Clariant

Clarient Corporation

4000 Monroe Road Charlotte, NC 28205 704.331.7090

Erin Russell Writer's Direct Dial No.: 704/331-7059 Fax No.: 704/331-7131 E-Mail: erin.russell@clariant.com

September 30, 2003

Ms. Deborah Brown
Chief of Toxics Pesticides and Federal Programs
EPA New England, Region 1
1 Congress Street, Suite 1100
Boston MA 02114-2023

Re: Clariant Corporation

Dear Ms. Brown:

Pursuant to our conversation earlier today, I am attaching a copy of the correspondence sent to Ms. Geraldine Gardner at EPA Headquarters concerning the discovery of elevated levels of PCBs in two pigment products manufactured at a Clariant facility in Coventry, Rhode Island. This should provide some background on our discovery of the issue and our initial actions in response. As we continue our response efforts we are coming across issues for which we need regulatory assistance. As I mentioned on the phone, we would like to arrange for a meeting with the appropriate Region 1 staff members to discuss the general situation, the response actions that we have undertaken and the issues we foresee with regard to the remaining activities addressing this issue. We have has some preliminary guidance from Peggy Reynolds at EPA Headquarters, however she suggested that Region 1 could take the lead in assisting us.

In general some issues we foresee that we will need to address are in the following areas: evaluating TRI and Tier II reporting, management of in-process product, reprocessing existing product that was not placed in commerce, and disposal issues. Of these issues the question of management of the product at various stages of production is of particular significance. This is an instance in which it does not appear that the regulations directly address some questions we have. For that reason we are hesitant to make an independent determination on how the regulations are interpreted in our circumstance. I am also sending by email to you copies of the email correspondence that addressed some of these issues in a preliminary way with Ms. Reynolds.

Over the next two weeks we are flexible in our availability to meet with you. I look forward to hearing from you.

Sincerely,

Erin Russell

c: Mike Teague John Paul



September 23, 2003

VIA FAX AND US MAIL Geraldine Gardner USEPA Headquarters Ariel Rios Building 2245A 1200 Pennsylvania Avenue, N. W. Washington, DC 20460

Re: Clariant Corporation
Telephone Contact C

Telephone Contact Confirmation Coventry Facility 500 Washington Street

Coventry, Rhode Island 02816

Dear Ms. Gardner:

I am writing as a follow up to my message yesterday and our phone conversation earlier today. As we discussed, Clariant has provided information concerning elevated levels of PCBs found in two pigment products. These products were manufactured at Clariant's Coventry facility in Coventry, Rhode Island and shipped to customers in a number of EPA regions.

This information was disclosed pursuant to the EPA Self-Audit Policy. Clariant meets the nine elements of the policy as follows:

- The discovery of non-compliance was found as part of a compliance management system. A recently initiated global program augmenting our corporate audit system in the United States called for testing of the pigment products from our Coventry facility. It was through this process that elevated levels of PCBs were discovered.
- 2. The discovery was not made through a legally mandated monitoring or sampling program. Again, it was through a self-initiated voluntary program.
- 3. Clariant's disclosure, initially made on September 22, 2003, was made within 21 days of discovery.
- The discovery and disclosure are made independent of a government or thirdparty action.
- 5. Clariant stopped producing the two products at issue. These product lines will not be resumed until they can produce pigments in compliance with the TSCA regulations. Clariant will provide necessary certifications under the audit policy regarding this factor.

Ms. Geraldine Gardner September 23, 2003 Page 2



- 6. Clariant will agree to take steps to prevent any recurrence of the violation. Clariant has already begun planning for a new program to augment existing programs and ensure compliance.
- 7. Clariant has had no PCB related violations at the Coventry facility.
- 8. Potential violations stemming from the activities described herein are not excluded from the audit policy.
- 9. Clariant will cooperate with the EPA in providing the information necessary to determine the applicability of the audit policy.

Clariant produces pigments in an excluded manufacturing process under TSCA. Clariant has historically tested the pigment intermediate for PCBs after the first step of the two-step manufacturing process. The intermediate has been consistently well below 50 ppm. Based on our lab testing and research it was not expected that PCBs would be generated in the second step of the manufacturing process. However, through a newly initiated program the end product underwent a series of analyses. PCBs were found at levels exceeding 50ppm. The presence of the PCBs at these levels was unexpected. We are researching the possible cause.

Clariant suspended manufacturing and shipment of the pigments. We are in the process of conducting meetings with our employees to inform them of the situation. Further, Clariant engaged outside occupational exposure and occupational medical experts to conduct a preliminary exposure assessment at the Coventry site, as well as at a sister division's manufacturing site where the pigments are used to make plastics colorants. Preliminary results show that employee exposure is negligible. This is due in part to the level of closure in the manufacturing process and to the PPE worn by workers on this process.

We have confirmed that there were no releases to water (via analytical from 2001, 2002, 2003) or to air (through calculations using EPA models). We do have material on site and are managing it for storage and disposal according to TSCA regulations. In storage there is no threat of spill.

We have implemented a communications plan that includes employees, customers and governmental officials. We are contacting our customers of this material with instructions not to use the product, and we are following up with storage instructions. Clariant will provide a hazardous waste contractor to go to the customer's sites, properly package the material and remove it for appropriate disposal.

Chris Barnard Mike Teague

Ms. Geraldine Gardner September 23, 2003 Page 3



In addition, Clariant is thoroughly reviewing the process for making the pigments to determine the likely source of the PCBs and how to eliminate it.

I am the Clariant contact for any questions related to this matter. My contact information is: Erin Russell, Clariant Corporation, 4000 Monroe Road, Charlotte, NC 28205. Telephone 704-331-7059; Fax 704-331-7131. I will be glad to provide further information or arrange to meet with EPA staff regarding this matter.

Sincerely,

Erin Russell

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Facsimile Transmission Cover Sheet

Erin Russell
Clariant Corporation
4000 Monroe Road
Charlotte NC 28205
Tel: 704/331-7059

Fax: 704/331-7131

erin.russell@clariant.com

To:

Peggy Reynolds

Firm:

US EPA

Fax No.:

202-566-0473

Phone:

202-566-0513

From:

Erin Russell

Date:

September 23, 2003

Subject:

Correspondence Attached

Number of pages, including cover:

4

I am still looking into the time of the FDA meeting on 9/29. It should be no earlier than 1pm. I'll try to have an answer to that in the morning. Attached is our notification letter sent earlier to Ms. Gardner. The information I have been able to find at this time is that the Clariant facilities using the pigment product (that is made in Rhode Island) are located in Delaware, Michigan, Minnesota, Illinois and Georgia. I hope this provides a good starting point for information.

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September 23, 2003

VIA FAX AND US MAIL Geraldine Gardner USEPA Headquarters Ariel Rios Building 2245A 1200 Pennsylvania Avenue, N. W. Washington, DC 20460

Re: Clariant Corporation

Telephone Contact Confirmation

Coventry Facility 500 Washington Street

Coventry, Rhode Island 02816

Dear Ms. Gardner:

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 management system. A recently initiated global program augmenting our
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Ms. Geraldine Gardner September 23, 2003 Page 2



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Ms. Géraldine Gardner September 23, 2003 Page 3



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Sincerely,

Erin Russell

c: Chris Barnard Mike Teague



Kimberly Tisa 09/26/03 06:29 AM

To: Peggy Reynolds/DC/USEPA/US@EPA cc: Marianne Milette/R1/USEPA/US@EPA

Subject: Re: Disclosure - Heads Up

Peggy,

Do we really need to do this through a .60(e) approval? If you read that provision, it implies meeting incinerator criteria (e.g. < 2ppm cleanup criteria, destruction efficiency requirements, etc). If this is a decontamination, can't we use 761.62(c)?

By the way, I'm sure we'd like additional info on this, especially as this is a self disclosure. I'm passing this along to Marianne who can followup with Geraldine.

Kimberly Tisa, PCB Coordinator (CPT) USEPA 1 Congress Street, Suite 1100 Boston, MA 02114-2023

617.918.1527 (PHONE) 617.918.0527 (FAX)

e-mail: tisa.kimberly@epa.gov

Peggy Reynolds

Peggy Reynolds

To: Kimberly Tisa/R1/USEPA/US@EPA

09/25/2003 04:59 PM

Subject: Re: Disclosure -- Heads Up

I was contacted by *Erin Russell*, counsel for *Clariant*, about two products (powder pigment & plastic pellets) that they manufacture under the excluded manufacturing process provision which contain inadvertently generated PCBs. This provision requires products that contain inadvertently generated PCBs to be in conformance with the restrictions re: PCB concentration when *leaving* the manufacturing site (i.e., the product must contain no more than an average of <25 ppm PCBs, with a 50 ppm maximum). Both products contain PCBs at concentrations at >50 ppm and have been shipped to Clarient's customers. Clariant contacted EPA to self-disclose. FOB's guidance to Clariant re: the >50 ppm products is that the >50 ppm products are waste: (1) dispose of the plastic pellets as PCB bulk product waste, and (2) dispose of the PCBs in the powder pigment via a 761.60(e) approval. Clean Harbors is being contracted to go to their customers' sites, package and ship the products for disposal.

FOB sought clarification of whether they intended to "reprocess" the powder pigment at the manufacturing site only (Coventry Plant in RI) or at other Clariant facilities as well. I have been informed that Clariant intends to reprocess the pigment at their RI plant; therefore, expect to receive a call in the near future. (Please see dialogue between EPA and Clariant below. I will also fax you a copy of the letter that was forwarded to Geraldine Gardner re: the self-disclosure.)

Peggy Reynolds Environmental Protection Specialist USEPA/OPPTS/OPPT/NPCD/FOB 1200 Pa. Ave., NW (Mail Code 7404T) Washington, DC 20460-0001 Telephone: 202-566-0513 Fax: 202-566-0473 reynolds.peggy@epa.gov

---- Forwarded by Peggy Reynolds/DC/USEPA/US on 09/25/03 04:28 PM ----

Peggy Reynolds

To: Erin.Russell@clariant.com

09/25/03 12:19 PM

Subject: Re: Disclosure

Okay; I'll give Region 1 a "heads-up" so that they know to expect to hear from you. The >50 ppm product should be manifested to the Coventry Plant and placed in a storage unit that is in conformance with the TSCA PCB storage requirements at 761.65(b)(1) or 761.65(b)(2), or possibly 761.65(c)(1) until disposal.

Peggy Reynolds Environmental Protection Specialist USEPA/OPPTS/OPPT/NPCD/FOB 1200 Pa. Ave., NW (Mail Code 7404T) Washington, DC 20460-0001 Telephone: 202-566-0513

Fax: 202-566-0473 reynolds.peggy@epa.gov

Erin.Russell@clariant.com



Erin.Russell@clariant.

To: Peggy Reynolds/DC/USEPA/US@EPA

cc: John.Paul@clariant.com, Mike.Teague@clariant.com

09/25/03 11:49 AM Subject: Re: Disclosure

Peggy - Based on the information you have provided, it would seem as though a meeting with the program office in Washington is not needed at this time. Rather, we will begin putting together our information to explain and support our request for reprocessing at the Coventry plant. Thank you for the contact name for Region 1. And I appreciate your quick response to us.

Erin Russell Senior Counsel 704-331-7059 erin.russell@clariant.com

> reynolds.peggy@epam ail.epa.gov

To:

Erin.Russell@clariant.com

cc:

John.Paul@clariant.com, Mike.Teague@clariant.com,

09/25/2003 09:41 AM

baney.tony@epamail.epa.gov,

lue.winston@epamail.epa.gov

Subject: Re: Disclosure

I'll start with the easier issue first -- plastic pellets. The only thing that I think I need to emphasis is the requirement to dispose of the pellets as PCB bulk product waste per Sec. 761.62 (e.g., TSCA approved facility such as a chemical waste landfill or incinerator or a hazardous waste landfill

permitted under either Sec. 3004 or 3006 of RCRA; a facility permitted, licensed or registered by a State as a municipal or non-municipal non-hazardous waste landfill; or under a risk-based disposal approval).

Powder pigment -- an exemption is not an option. First, the >50 ppm product is viewed as PCB waste by EPA (i.e., product left the manufacturing site at >25 ppm), and an exemption is not needed to process waste. Secondly, an exemption must be done via rulemaking, a process which has taken in excess of 2 years to complete. Under the PCB regulations, PCB waste must be disposed of within one year.

The 761.60(e) disposal option requires the submission, and EPA's approval, of a disposal application which provides the details of the "disposal" (reprocessing) process. If the process Clariant intends to follow can/will be conducted at multiple facilities, the application would come to Headquarters. If the disposal is to be handled at one facility, the application should be submitted to the appropriate EPA Regional Toxics Office (e.g., Region 1 for Rhode Island). Kim Tisa is the PCB Coordinator for Region 1; I have not yet spoken to her about the Clariant situation.

I'm available until about 12:30 today and then I'll be out of reach for the rest of the week. Please call, ASAP if you decide a meeting at Headquarters would be useful.

Peggy Reynolds
Environmental Protection Specialist
USEPA/OPPTS/OPPT/NPCD/FOB
1200 Pa. Ave., NW (Mail Code 7404T)
Washington, DC 20460-0001
Telephone: 202-566-0513
Fax: 202-566-0473
reynolds.peggy@epa.gov

Erin.Russell@clar
iant.com To: Peggy
Reynolds/DC/USEPA/US@EPA

CC:

Mike.Teague@clariant.com, John.Paul@clariant.com 09/24/03 05:04 PM Subject: Re: Disclosure

Thank you for the information you have provided. As you note, there are several issues with regard to the product that we are reviewing. In order

to keep things as clear as I can, I'll list them separately.

With regard to reprocessing of the pigment materials.

We are interested in clarifying and confirming whether the plant in Coventry, Rhode Island can re-process the off-spec pigment product. We believe that with reprocessing, the pigment product can be brought into compliance with the standards set out in the excluded manufacturing process

definition. This work would be done in a closed system at the Coventry facility only. PCBs removed in the reprocessing would be disposed of in accordance with the regs. Based on my reading of the regulations there are

two parts that may be applicable to this concept. One is the possibility

of receiving an exemption, under 750.10 or 750.30, that could cover this activity, the second is relying on the provisions of the decontamination standards and procedures as guidance. We would also be interested in reviewing the possibility of application of 761.60(e) as an option, as you

note in your email.

With regard to Clariant's plastic pellets.

We do not know any method for extracting PCBs from the Masterbatch product

I described. We are arranging for pickup, packaging, and disposal of these

with Clean Harbors. There are multiple sites that will be disposing of this product, but it does not appear that there are regulatory questions with regard to this procedure, at this time.

Based on what we are looking for with regard to reprocessing at one location, I'll ask you for guidance on whether Region 1 or EPA Headquarters is the better place to start. Thanks again for your assistance.

Erin Russell Senior Counsel Clariant Corporation 4000 Monroe Road Charlotte NC 28205

704-331-7059 erin.russell@clariant.com

reynolds.peggy@epam

ail.epa.gov

To:

erin.russell@clariant.com

cc:

Ms. Russell: Thank you for sending me a copy of your letter to Geraldine Gardner. Since the regulations require that inadvertently generated PCBs in products leaving the manufacturing site have an annual average of <25 ppm PCBs, with a 50 ppm maximum, I note that Clariant's plans (last paragraph, p. 2) include packaging the material at the customer's sites (e.g., Clariant facilities as well as other customers) for removal and disposal. Therefore, the purpose of meeting with EPA, as I understand it, would be to determine how the >50 ppm PCB products must be managed (i.e., disposed). There are no self-implementing provisions in the regulations which would allow Clariant to "decontaminate" the >50 ppm products without first obtaining a disposal approval. Presumably, that is why Ms. Gardner suggested you contact me.

Since removal of the PCBs from the plastic pellets is not feasible, disposal options would include disposal as a PCB bulk product waste under the provision at Sec. 761.62 (e.g., TSCA approved facility such as a chemical waste landfill or incinerator or a hazardous waste landfill permitted under either Sec. 3004 or 3006 of RCRA; a facility permitted, licensed or registered by a State as a municipal or non-municipal non-hazardous waste landfill; or under a risk-based disposal approval).

However, the alternate disposal approval process under Sec. 761.60(e) may be a potential disposal option for the >50 ppm powder pigment. If appropriate, this type of approval would prescribe procedures under which Clariant could use a solvent to remove the PCBs, reclaim the pigment, and then dispose of the waste solvent and PCBs.

The question I have is whether the PCB removal is expected to occur at the manufacturing site only (Rhode Island -- EPA Region 1) or at the other Clariant facilities as well (Delaware, Michigan, Minnesota, Illinois and Georgia -- in EPA Regions 3, 5, 4). The answer to this question is the determining factor in whether further discussions should occur with EPA Region 1 or EPA Headquarters. A meeting in DC may not be necessary if the PCB disposal activities will be limited to one location. Therefore, would you please clarify the purpose of a meeting, if a meeting is still desired.

Peggy Reynolds
Environmental Protection Specialist
USEPA/OPPTS/OPPT/NPCD/FOB
1200 Pa. Ave., NW (Mail Code 7404T)
Washington, DC 20460-0001
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reynolds.peggy@epa.gov